

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Spiros Jamas, D. Davidson Easson Jr. and Gary R. Ostroff

Continuation Application of

Application No.: 09/841,179

Filed: April 24, 2001

Title: UNDERIVATIZED, AQUEOUS SOLUBLE β (1-3) GLUCAN, COMPOSITION
AND METHOD OF MAKING SAME

Date: 11/21/03

EXPRESS MAIL LABEL NO. EV 052029702 US

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ All copies of cited references were entered in prior applications, U.S. Application Nos. 09/841,179, 08/373,251, 09/326,513 and 07/934,015 to which priority under 35 U.S.C. 120 is claimed. The earlier applications contains copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) ☐ under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By _____

Alice O. Carroll

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Concord, MA 01742-9133

Dated: _____

November 21, 2003

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION November 21, 2003 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 2732.1016-029		APPLICATION NO. Cont. App of 09/841,179	
	APPLICANT Spiros Jamas <i>et al.</i>			
	FILING DATE	CONFIRMATION NO.	GROUP	

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	AA	4,810,646	03/07/89	Jamas <i>et al.</i>
	AB	4,761,402	08/02/88	Williams <i>et al.</i>
	AC	4,739,046	04/19/88	DiLuzio <i>et al.</i>
	AD	4,138,479	02/06/79	Truscheit <i>et al.</i>
	AE	4,237,266	12/02/80	Sugiura <i>et al.</i>
	AF	4,707,471	11/17/87	Larm <i>et al.</i>
	AG	5,032,401	07/16/91	Jamas <i>et al.</i>
	AH	5,057,503	10/15/91	Czop <i>et al.</i>
	AI	5,322,841	11/02/92	Jamas <i>et al.</i>
	AJ	5,320,849	06/14/94	Hagiwara <i>et al.</i>
	AK	5,488,040	01/30/96	Jamas <i>et al.</i>
	AA2	5,532,223	07/02/96	Jamas <i>et al.</i>
	AB2	5,622,939	04/22/97	Jamas <i>et al.</i>
	AC2	3,943,247	03/09/76	Komatsu <i>et al.</i>
	AD2	5,504,079	04/02/96	Jamas <i>et al.</i>
	AE2	5,401,647	03/28/95	Tanaka <i>et al.</i>
	AF2	5,783,569	7/21/98	Jamas <i>et al.</i>
	AG2	5,817,643	10/06/98	Jamas <i>et al.</i>
	AH2	4,975,421	12/04/90	Williams <i>et al.</i>
	AI2	5,474,984	12/12/95	Tanaka <i>et al.</i>
	AJ2	4,946,450	08/07/90	Erwin
	AK2	4,992,540	02/12/91	Jamas <i>et al.</i>
	AA3	5,663,324	09/02/97	Jamas <i>et al.</i>
	AB3	5,633,369	05/27/97	Jamas <i>et al.</i>
	AC3	5,811,542	09/22/98	Jamas <i>et al.</i>

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PTO-1449 RERRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION November 21, 2003 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 2732.1016-029		APPLICATION NO. Cont. App of 09/841,179	
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FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES NO	
	AL	59210901	06-APR-95	Japan (Abstract)	X	
	AM	59045301	21-JUN-84	Japan (Abstract)	X	
	AN	56076401	11-SEP-81	Japan (Abstract)	X	
	AO	55071701	12-AUG-80	Japan (Abstract)	X	
	AP	20764118	02-DEC-81	Great Britain		
	AQ	91/03495	21-MAR-91	PCT International		
	AL2	WO 94/04163	03-MAR-94	PCT International		
	AM2	WO 91/03248	31-MAR-91	PCT International		
	AN2	0463540	02-JAN-92	EPO		
	AO2	94/03498	17-FEB-94	PCT International		
	AP2	92/13896	20-AUG-92	PCT International		
	AQ2	94/03500	17-FEB-94	PCT International		
	AL3	0416343	13-MAR-91	EPC		
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AR	Janusz, M.J., <i>et al.</i> , "Isolation of Soluble Yeast β -Glucans that Inhibit Human Monocyte Phagocytosis Mediated by β -Glucans Receptors," <i>J. Immunol.</i> , 137:3270-3276 (1986).	
AS	Manners, D.J., <i>et al.</i> , "The Structure of a β -(3)-D-Glucan from Yeast Cell Walls," <i>Biochem. J.</i> , 135:19-30 (1973).	
AT	Fleet, G.H., <i>et al.</i> , "Isolation and Composition of an Alkali-Soluble Glucan from the Cell Walls of <i>Saccharomyces cerevisiae</i> ," <i>J. Gen. Microbio.</i> , 94:180-192 (1976).	
AU	Miyazaki, T., <i>et al.</i> , "Structural Examination of Antitumour, Water-Soluble Glucans from <i>Grifora umbellata</i> by Use of Four Types of Glucanase," <i>Carbohydrate Research</i> , 65:235-243 (1978).	
AV	Reiskind, J.B. and Mullins, J.T., "Molecular Architecture of the Hyphal Wall of <i>Achlya ambisexualis</i> Raper. II. Ultrastructural Analyses and a Proposed Model," <i>Can. J. Microbiol.</i> , 27:1100-1105 (1981).	
AW	Latgé, J.P., <i>et al.</i> , "Composition Chimique et Ultrastructure des Parois des Hyphaux et des Azygospores de <i>Conidiobolus obscurus</i> ," <i>Can. J. Microbiol.</i> , 30:1507-1421 (1984).	
AX	Sherwood, E.R., <i>et al.</i> , "Soluble Glucan and Lymphokine-Activated Killer (LAK) Cells in the Therapy of Experimental Hepatic Metastases," <i>Chemical Abstracts</i> , 108:179752v (1988).	
AY	Hara, C., <i>et al.</i> , "A Branched (1-3)- β -D-Glucan from a Water Extract of <i>Dictyophora indusiata</i> FISCH," <i>Carb. Res.</i> , 145:237-246 (1986).	
AZ	Goldman, R., "Induction of a β -1,3-D-Glucan Receptor in P388D1 Cells Treated with Retinoic Acid of 1,25-dihydroxyvitamin D ₃ ," <i>Immunology</i> , 63:319-324 (1988).	
AR2	Konopski, A., <i>et al.</i> , "Phagocytosis of β -1,3-D-Glucan-Derivatized Microbeads by Mouse Peritoneal Macrophages Involves Three Different Receptors," <i>Scand. J. Immunol.</i> , 33:297-306 (1991).	
AS2	Williams, D.L., <i>et al.</i> , "Development of a Water-Soluble, Sulfated (1-3)- β -D-Glucan Biological Response Modifier Derived from <i>Saccharomyces cerevisiae</i> ," <i>Carbohydrate Research</i> , 235:247-257 (1992).	
AT2	Williams, D.L., <i>et al.</i> , "A Sequential Multi-Assay Protocol for the Preclinical Assessment of Natural Product Complex Carbohydrate Immunomodulators," <i>Develop. Biol. Standard</i> , 77:129-136(1992).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AU2	Williams, D.L., <i>et al.</i> , Development, Physiochemical Characterization and Preclinical Efficacy Evaluation of a Water Soluble Glucan Sulfate Derived from <i>Saccharomyces cerevisiae</i> , "Immunopharmacology, 22:139-156 (1991).	
AV2	Bacon, J., <i>et al.</i> , "The Glucan Components of the Cell Wall of Baker's Yeast (<i>Saccharomyces cerevisiae</i>) Considered in Relation to its Ultrastructure," <i>Biochem. J.</i> , 114:557-567 (1969).	
AW2	Vestnick Federalniho Uradu Pro Vynalezky, 10:111 (1989).	
AX2	Vestnick Federalniho Uradu Pro Vynalezky, 11:122-123 (1989).	
AY2	Onderdonk, A.B., <i>et al.</i> , "Anti-Infective Effect of Poly- β 1-6-Glucotrisyl- β 1-3-Glucopyranose Glucan <i>In Vivo</i> ," <i>Infect. Immun.</i> , 60:1642-1647 (1992).	
AZ2	Abel, G. and Czop, J.K., "Activation of Human Monocyte GM-CSF and TNF- α Production by Particulate Yeast Glucan," International Congress for Infectious Diseases, Montreal Canada (Abstract) July 15-19, 1990.	
AR3	Chihara, G., <i>et al.</i> , "Lentinan as a Host Defense Potentiator (HPD)," <i>Int. J. Immunotherapy</i> , 4:145-154 (1989).	
AS3	Sherwood, E.R., <i>et al.</i> , "Enhancement of Interleukin-1 and Interleukin-2 Production by Soluble Glucan," <i>Int. J. Immunopharm.</i> , 9(3):261-267 (1987).	
AT3	Williams, D.L., <i>et al.</i> , "Pre-clinical Safety Evaluation of Soluble Glucan," <i>Int. J. Immunopharm.</i> , 10(4):405-414 (1988).	
AU3	Browder, W., <i>et al.</i> , "Beneficial Effect of Enhanced Macrophage Function in the Trauma Patient," <i>Ann. Surg.</i> , p. 605-613 (1990).	
AV3	Jamas, <i>et al.</i> , "A Novel Class of Macrophage-Activating Immunomodulators," ACS Symposium Series, <i>Polymeric Drugs and Delivery Systems</i> , Chapter 5, pp. 44-51 (1991).	
AW3	Shiota, M., <i>et al.</i> , "Comparison of β -Glucan Structures in a Cell Wall Mutant of <i>Saccharomyces cerevisiae</i> and the Wild Type," <i>J. Biochem.</i> , 98:1301-1307 (1985).	
AX3	Jamas, <i>et al.</i> , "PGG-A Novel Class of Macrophage Activating Immunomodulators," International Congress for Infectious Diseases, Montreal, Canada (Abstract), July 15-19, 1990.	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AY3	Katzen, <i>et al.</i> , "PGG, a Glucose Polymer, Primes Interleukin-1 and Tumor Necrosis Factor Production," International Congress for Infectious Diseases, Montreal, Canada (Abstract), July 15-19, 1990.	
AZ3	Shah, <i>et al.</i> , "Influence of PGG on the Phagocytosis of <i>Staphylococcus aureus</i> or <i>Escherichia coli</i> ," International Congress for Infectious Diseases, Montreal, Canada (Abstract), July 15-19, 1990.	
AR4	Onderdonk, A.B., "Effect of a New Carbohydrate Polymer on Survival in a Mouse Model for Experimental <i>E. coli</i> Sepsis," International Congress for Infectious Diseases, Montreal, Canada (Abstract), July 15-19, 1990.	
AS4	Arbo, A. and Santos, J.I., "Effect of PGG on Neutrophil (PMN) Function in Experimental Malnutrition," International Congress for Infectious Diseases, Montreal, Canada (Abstract), July 15-19, 1990.	
AT4	Onderdonk, A.B., <i>et al.</i> , "Protective Effect of a New Carbohydrate Polymer in a Rat Model for Experimental Intraabdominal Sepsis," First International Congress on Biological Response Modifiers, Quebec, Canada, (Abstract), March, 1991.	
AU4	Lagrange, P.H. and Fourgeaud, M., "Enhanced Natural Resistance Against Severe Disseminated <i>Candida albicans</i> ," <i>Int'l J. Experimental Clin. Chemotherapy</i> , 40(1):48-55 (1991).	
AV4	Sakurai, <i>et al.</i> , "Intravenously Administered (1-3)- β -D-Glucan, SSG, Obtained from <i>Sclerotinia sclerotiorum</i> IFO9395 Augments Murine Peritoneal Macrophage Function <i>In Vivo</i> ," <i>Chem. Pharm. Bull.</i> , 40(8):2120-2124 (1992).	
AW4	Jamas, S., <i>et al.</i> , "PGG-A Novel Class of Macrophage Activating Immunomodulators," <i>Polymer Preprints</i> , 31:194-195 (1990).	
AX4	Sasaki, <i>et al.</i> , "Antitumor Activity of Degraded Products of Lentinan: Its Correlation with Molecular Weight," <i>Gann</i> , 67:191-195 (1976).	
AY4	Di Luzio, <i>et al.</i> , "Comparative Tumor-Inhibitory and Anti-Bacterial Activity of Soluble and Particulate Glucan," <i>Int. J. Cancer</i> , 24:773-779 (1979).	
AZ4	Burgaleta, C. and Golde, D.W., "Effect of Glucan of Granulopoiesis and Macrophage Genesis in Mice," <i>Cancer Research</i> , 37:1739-1742 (1977).	
AR5	Kenyon, A.J., "Delayed Wound Healing in Mice Associated with Viral Alteration of Macrophages," <i>Am. J. Vet. Res.</i> , 44(4):652-656 (1983).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AS5	Babineau, T., <i>et al.</i> , "Randomized Phase I/II Trial of a Macrophage-Specific Immunomodulator PGG-Glucan (Betafectin™) in High Risk Surgery Patients," Clinical Congress of the American College of Surgeons, San Francisco, CA, October 11, 1993.	
AT5	Babineau, T., <i>et al.</i> , "Randomized Multicenter Phase I/II Trial of a Macrophage-Specific Immunomodulator (PGG-Glucan) in High Risk Surgery Patients," Surgical Infection Society Meeting, April, 29, 1994.	
AU5	Adachi, Y., <i>et al.</i> , "Enhancement of Cytokine Production by Macrophages Stimulated with (1-3)-β-D-Glucan, Grifolan (GRN), Isolated from <i>Grifola frondosa</i> ," <i>Biol. Pharm. Bull.</i> , 17(12):1554-1560 (1994).	
AV5	Babineau, T.J., <i>et al.</i> , "A Phase II Multicenter, Double-blind, Randomized, Placebo-Controlled Study of Three Dosages of an Immunomodulator (PGG-Glucan) in High Risk Surgical Patients", <i>Archives of Surgery</i> , 129:1204-1210 (1994).	
AW5	Babineau, T.J., <i>et al.</i> , "Randomized Phase I/II Trial of a Macrophage-Specific Immunomodulator (PGG-Glucan) in High Risk Surgical Patients", <i>Annals of Surgery</i> , 220(5):601-609 (1994).	
AX5	Norton, J.A., "Biological Therapy of Sepsis", <i>Annals of Surgery</i> , 220(5):599-600 (1994).	
AY5	"Tumor Necrosis Factor: A Biological Enigma," <i>Science Impact</i> , pp. 5-6, June 1989.	
AZ5	Dinarello, C.A. and Neta, R., "An Overview on Interleukin-1 as a Therapeutic Agent", <i>Biotherapy</i> , 1:245-254 (1989).	
AR6	Van der Meer, J.W.M., <i>et al.</i> , "Concentrations of Immunoreactive Human Tumor Necrosis Factor Alpha Produced by Human Mononuclear Cells In Vitro," <i>Journal of Leukocyte Biology</i> , 43:216-223 (1988).	
AS6	Dinarello, C.A., "Interleukin-1," <i>Reviews of Infectious Diseases</i> , 6(1):51-95 (1984).	
AT6	Duvic, M., <i>et al.</i> , "Glucan-Induced Keratoderma in Acquired Immunodeficiency Syndrome," <i>Arch Dermatol.</i> , 123:751-756	
AU6	Adachi, Y., <i>et al.</i> , "Macrophage Activation in Vitro by Chemically Cross-Linked (1-3)-β-D-Glucans," <i>Chem. Pharm. Bull.</i> , 38(4):988-992 (1990).	
AV6	Sietsma, J.H. and Wessels, J.G.H., "Solubility of (1-3)-β-D-Glucan in Fungal Walls: Importance of Presumed Linkage between Glucan and Chitin", <i>J. Gen. Microbiology</i> , 125:209-212 (1981).	

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